Applic Rec'd____ Hum Subjects Rec'd____DUA Rec'd____Rev& Approved_____ Added to Req List____ Guidelines Sent____ Networked____

APPLICATION: COOPERATIVE HUMAN TISSUE NETWORK

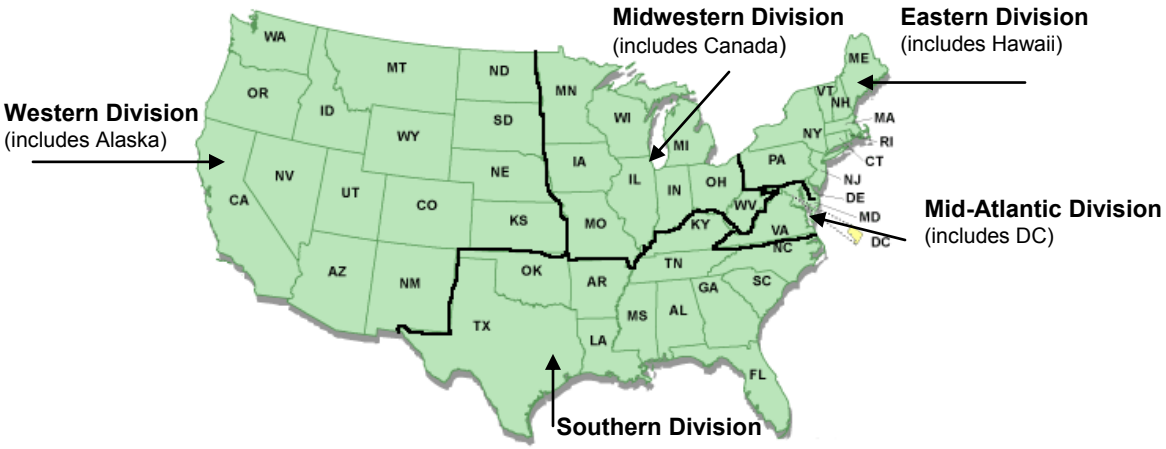
I. DIRECTIONS – This application is intended for the use and processing of samples utilized by the laboratory and/or personnel that fall under the supervision of the PI listed in the application. Any transfer of samples or aliquots to personnel or laboratories that are not under the supervision of the indicated PI requires the following:

- An explanation of the need to transfer the materials and benefit to the investigator's research.
- A copy of the enclosed CHTN agreement page signed by the collaborator.
- A copy of the collaborator's IRB approval unless the collaborator is covered under the IRB approval granted for the project proposed in this application.

The CHTN does not supply samples to banks solely for distribution to third party researchers; those researchers should be encouraged to apply to the CHTN directly.

The information requested in these forms is necessary in order to document correctly your request for tissue and other services and to ensure that the CHTN operates within the guidelines of the National Cancer Institute. When submitting a written request for services:

1. Please print neatly or type.
2. Please be specific about your requirements for handling tissue samples from the time the specimen is collected until it is delivered to your lab (i.e.; need for sterility, transport media, refrigeration status, etc.)
3. Patient identity is confidential. Samples will be coded and delivered at a processing fee of $40/sample for investigators at academic institutions and $80/sample for investigators at non-academic institutions, plus shipping costs.
4. Investigators must have human use approval to receive tissue from the CHTN. Either full or expedited approval can be obtained from your Institutional Review Board (Human Use Committee). **A COPY OF THE HUMAN SUBJECTS APPROVAL SHOULD BE ATTACHED TO THIS FORM.** An annual human subjects review is required and must be forwarded to the CHTN in order to maintain your eligibility to receive tissue.
5. For pediatric tissue (available nationwide) please complete this application and mail directly to Nationwide Children's Hospital (see address below).
6. For additional information call the Division for your state (see map below). Send completed forms to this Division.



Eastern Division University of Pennsylvania Medical Center 3400 Spruce St. 566 Dulles Philadelphia, PA 19104-4283 Tel: 215-662-4570 Fax: 215-614-0251 dfitzsim@mail.med.upenn.edu	**Mid-Atlantic Division** University of Virginia Health System CHTN Mid-Atlantic Division Department of Pathology P.O. Box 800214 Charlottesville, VA 22908-0214 Tel: 434-924-9879 Fax: 434-924-9438 crumpel@virginia.edu	**Midwestern Division** The Ohio State University Department of Pathology, Tissue Procurement 2001 Polaris Parkway Columbus, OH 43240 Tel: 614-293-6906 Fax: 614-293-7013 scott.jewell@osumc.edu
Pediatric Division Nationwide Children's Hospital 700 Children's Drive Room W135 Columbus, OH 43205 Tel: 614-722-2714 Fax: 614-722-2897 laura.monovich@nationwidechildrens.org	**Southern Division** Tissue Procurement, ZRB449 University of Alabama at Birmingham 1530 Third Ave South Birmingham, AL 35294-0007 Tel: 205-934-6071 Fax: 205-934-0816 sexton@uab.edu	**Western Division** Vanderbilt University Medical Center 4918 TVC Boulevard 22nd & Pierce Ave. Nashville, TN 37232-5310 Tel: 615-322-7486 Fax: 615-322-4741 kerry.wiles@vanderbilt.edu

II. Investigator Data

A. Principal Investigator _____
Last Name *First Name* *Middle Initial* *Degree*

Investigator's Title_____

Primary Mailing Address (Street/Bldg/Room#)_____

_____

Department_____

Institution_____

City_____State_____Zip_____

Phone (Day)_____(Nights/Weekends)_____

Fax #_____E-mail_____

Contact Person_____Lab Phone_____E-mail_____

B. Shipping Address (*if different from above)*_____

Department_____

Street/Bldg/Room#_____

City_____State_____Zip_____

C. Billing Information: Is a purchase order (PO) required for shipment of specimens to your institution?

Yes_____No_____ If so, please list name of contact for PO:_____

Name_____Phone_____

Currently invoices are included with the tissue shipment to the shipping address listed in Section B. If you would like the original invoice to be mailed to another location (e.g. your billing department), please enter that address below. A copy of the invoice will also be included with your shipment.

Billing Address (*If different from the shipping address)*_____

Department_____

Street/Bldg/Room#_____

City_____State_____Zip_____

(Shipping charges will be added to your invoice unless you provide a Federal Express number).

Federal Express Number_____

III. Funding Information

Tissues will be provided to investigators on a rotating basis in the following priority order:

1. Peer reviewed funded investigators (including Federal and National laboratories)
2. New investigators and academic investigators developing new research projects.
3. Other investigators.

A. To help determine your priority, please include <u>your major research grant</u>. Institutional and other funding sources may be listed. If you are currently unfunded, please indicate below:

<u>Funding Source</u> <u>Period of Support</u>

B. Please provide the title and a short research summary of the proposed research on the tissues you are requesting from the CHTN (*use separate page*).

IV. Services Requested (Please copy this page as needed for multiple requests).

A. Human Tissue Specimen Criteria

1. Anatomic Site or Tissue Type_____

____Malignant _____Benign _____Normal _____Diseased _____ Other_____

If malignant is selected, please specify: _____ Primary and/or mets; _____ Primary only; _____ Mets only

_____Any malignant _____specify type of malignancy:_____

2. Is matched uninvolved tissue from the same patient required? _____Yes _____No _____If available

3. Will you accept tissue from patients previously treated with _____Radiation _____Chemotherapy?

4. Must specimen be sterile? _____Yes _____No _____ As clean as possible

5. Gender: _____Male _____Female _____Either

6. Tissue Source:

_____Surgical - Must be collected/processed within ____hrs of sx OR ____time constraint not applicable

_____Autopsy - Must be collected within _____ hours after death

7. Patient Limitations (i.e., age, race, or other limiting characteristics):_____

_____

8. Amount of tissue required (minimum to maximum size or dimension):_____

9. Frequency tissue is needed:_____

10. Total number of samples needed:_____

11. Requested starting date to receive tissue:_____

B. Preparation and Preservation of Samples (*please mark only those that apply*)

_____**Fresh.** Indicate media requirements:

_____Transport Media; _____ Saline; _____ Dry; _____ Other:_____

(if preference for transport media, e.g. RPMI, L-15, DMEM, please indicate): _____

Wrap in Gauze? ____Yes ____ No

Add supplements:

_____Antibiotics (indicate type & amount)

_____Fetal Calf Serum (indicate percentage)

_____Fungizone (indicate amount)

Shipping Requirements (wet ice, room temp. etc.)

_____**Frozen** [Indicate freezing requirements (fresh-frozen, OCT, etc.)]_____

_____**Fixed**. [Indicate fixative requirements (10% BNF, etc.)]_____

Will you accept Saturday deliveries, if notified? _____Yes _____No _____Sometimes, if notified

Sample Information Required: (Anatomic site of tissue, provisional diagnosis, final diagnosis, quality control diagnosis and patient age, sex and race [if available] will be provided for all samples.) **Additional patient information may be available, but you must request it in this application and justify its necessity for your research. Requests for additional information cannot be accepted after the application is received.**

(NOTE: please notify your division coordinator ASAP if your needs change).

AGREEMENT FOR USE OF TISSUE

The recipient/investigator agrees that the tissues provided by the Cooperative Human Tissue Network (CHTN) will be used only for the purposes specified in this application. The recipient agrees not to attempt to obtain information identifying the individuals providing tissues to the CHTN. The recipient agrees that it shall not sell any portion of the tissues provided by the CHTN, or products directly extracted from these tissues (e.g. protein, mRNA or DNA). The recipient agrees that it shall not transfer tissue (or any portion thereof) supplied by the CHTN to third parties without the prior written permission of the CHTN.

The recipient understands that while the CHTN attempts to avoid providing tissues that are contaminated with highly infectious agents such as hepatitis and HIV, all tissues should be handled as if potentially infectious. The individuals who have supplied tissue to the CHTN have not agreed to have clinical tests performed on this tissue (e.g. for the presence of infective agents such as hepatitis), therefore, the recipient agrees not to perform such tests on the tissues supplied by the CHTN**.** The recipient acknowledges that the institution where the tissue will be used follows OSHA regulations for handling human specimens and will instruct their staff to abide by those rules. The recipient further agrees to assume all responsibility for informing and training personnel in the dangers and procedures for safe handling of human tissues.

Tissues are provided as a service to the research community without warranty of merchantability or fitness for a particular purpose or any other warranty, express or implied. The CHTN accepts no responsibility for any injury (including death) damages or loss that may arise either directly or indirectly from their use.

The recipient agrees to acknowledge the contributions of the Cooperative Human Tissue Network in all publications resulting from the use of these tissues. Recommended wording to the methods or acknowledgement section is as follows: *"Tissue samples were provided by the Cooperative Human Tissue Network which is funded by the National Cancer Institute. Other investigators may have received specimens from the same subjects."*

When tissue is to be used at State Institutions: The institution agrees to be responsible for any claims, costs, damages, or expenses resulting from any injury (including death), damage or loss that may arise solely from the receipt, handling, storage and use of tissues received from the CHTN to the extent permitted under the laws of this State. The undersigned warrants that they have authority to execute this agreement on behalf of the recipient institution.

When tissue is to be used at U.S. Government Agencies: The US government assumes all risks and responsibilities in connection with the receipt, handling, storage and use of tissues received from the Cooperative Human Tissue Network. The United States assumes liability for any claims, damages, injury or expense arising from the use of the material or any derivative, but only to the extent provided under the Federal Tort Claims Act (28 U.S.C. Chap. 171).

When tissue is to be used by all other institutions: The institution agrees to assume all risks and responsibility in connection with the receipt, handling, storage and use of tissues from the Cooperative Human Tissue Network. It further agrees to indemnify and hold harmless the Cooperative Human Tissue Network and the United States Government from any claims costs, damages or expenses resulting from the use of the tissues provided by the CHTN. The undersigned warrant that they have authority to execute this agreement on behalf of the recipient institution.

BY MY SIGNATURE I AGREE TO THE TERMS SET FORTH IN THE ABOVE AGREEMENT

_____	_____	_____
Typed Name of Recipient	Agency	Typed Name of Official Authorized to Sign for the Agency
_____	_____	_____
Signature of Recipient/Date	Division or Department	Authorized Signature/Date

UPON RECEIPT OF THESE SIGNED UNDERSTANDINGS AND THE INFORMATION REQUESTEDABOVE, THE COOPERATIVE HUMAN TISSUE NETWORK WILL CONSIDER THIS REQUEST AND ALL FUTURE REQUESTS FOR TISSUE. Specific questions about your application should be directed to your regional coordinator. Other questions may be directed to the NCI Program Director, Ms. Kelly Kim at 301-435-0509.

CHTN HIPAA Compliance Policy
Requirement for Data Use Agreement

The Department of Health and Human Services (DHHS) issued the HIPAA "Privacy Rule," on August 14, 2002 (http://www.hhs.gov/ocr/). This federal regulation governs the protection of individually identifiable health information. The Rule was enacted to increase the privacy and confidentiality of health information on identified individuals, and to regulate known and unanticipated risks to privacy that may accompany the use and disclosure of such information. The Privacy Rule does not apply to specimens *per se*, but does apply to some of the health information that may be provided with the specimen. The CHTN has always protected the identity of patients from whom specimens are obtained. However, the Privacy Rule imposes new requirements on the use of information associated with the specimens. In order to meet the requirements of the Privacy Rule, the CHTN has implemented a new requirement, a Data Use Agreement, in order to receive specimens with associated data. HIPAA applies to all of the CHTN institutions that supply tissues and patient information to you as an investigator and all CHTN divisions must follow their institutional policies.

The Data Use Agreement will permit you to receive tissue and associated patient information from any division of the CHTN from which such data is available. Because the CHTN Western Division, based at Vanderbilt University, only supplies anonymized, de-identified patient information, they are not listed in the agreement.

Investigators who require patient information beyond that routinely provided or clinical outcome data must inform the CHTN at the time that tissues are requested. This is necessary because of CHTN operating procedures and local IRB requirements for protecting human subjects and patient privacy and confidentiality. As a result of HIPAA regulations, some Divisions may apply more stringent requirements for obtaining such information. Similarly, local requirements for protecting patient privacy and confidentiality may limit the ability of some CHTN divisions to obtain copies of pathology reports for samples previously shipped.

Please include the attached signed Data Use Agreement with the application that is submitted to request services of the CHTN.

DATA USE AGREEMENT BETWEEN COOPERATIVE HUMAN TISSUE NETWORK (CHTN) INSTITUTIONS PROVIDING A LIMITED DATA SET AND LIMITED DATA SET RECIPIENTS

This Data Use Agreement ("Agreement") is designed to permit the use of a Limited Data Set for research pursuant to the Standards for Privacy of Individually Identifiable Health Information, (Privacy Rule) 45 CFR Parts 160 and 164. All terms used in this agreement are as defined in the Privacy Rule.

This Agreement is made and entered into as of this _____ day of _____, 20_____ by and between The Board of Trustees of the University of Alabama for the University of Alabama at Birmingham, the University of Pennsylvania Health System and the University of Pennsylvania School of Medicine, The Rector and Visitors of the University of Virginia for the University of Virginia Medical Center, The Ohio State University, and the Columbus Children's Research Institute, ("Covered Entities"), which operate as various divisions of the Cooperative Human Tissue Network (CHTN) and _____ ("Data Recipient").

1. This Agreement sets forth the terms and conditions pursuant to which the Covered Entities will Disclose certain Protected Health Information (PHI) to the Data Recipient. PHI may include associated histopathologic, demographic, and clinical data that have been rendered a Limited Data set in compliance with 45 CFR 164.514(e)(1).
2. Except as otherwise specified herein, the Data Recipient may make Uses and Disclosures of the Limited Data Set consistent with the purpose of the research as described within their research application to the CHTN.
3. The individuals, or classes of individuals, who are permitted to Use or receive the Limited Data Set include the Data Recipient and other researchers or individuals directly involved with the research project described within their research application to the CHTN.
4. The Data Recipient agrees to not Use or Disclose the Limited Data Set for any purpose other than the Research Project or as Required by Law.
5. The Data Recipient agrees to use appropriate safeguards to prevent Use or Disclosure of the Limited Data Set other than as provided for by this Agreement.
6. The Data Recipient agrees to report to the Covered Entities any Use or Disclosure of the Limited Data Set not provided for by this Agreement, of which it becomes aware, including without limitation, any Disclosure of PHI to an unauthorized subcontractor.
7. The Data Recipient agrees to ensure that any agent, including a subcontractor, to whom it provides the Limited Data Set, agrees to the same restrictions and conditions that apply through this Agreement to the Data Recipient with respect to such information.
8. The Data Recipient agrees not to attempt to identify or contact the individual(s) to whom the Limited Data Set applies.
9. This agreement may be terminated by the Covered Entities upon five (5) days written notice to the Data Recipient if the Data Recipient materially breaches any provision contained in this Agreement and such breach is not cured within the five (5) day period. The Data Recipient acknowledges that if efforts to cure the breach are unsuccessful, the Covered Entities may discontinue disclosure of Protected Health Information and report the problem to the Secretary of the Department of Health and Human Services.
10. The terms of this agreement can be changed only by written modification signed by both parties.

DATA RECIPIENT

_____ _____

Name of Principal Investigator (Typed or Printed) Authorized Signature

_____ _____

Title Date